UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **ALL PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

ETHICON'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF CHRISTINA PRAMUDJI, M.D.

INTRODUCTION

Plaintiffs do not challenge Dr. Pramudji's expertise as a pelvic surgeon. *See, generally*, Plaintiffs' Motion to Exclude [Doc. No. 2035] and Memorandum in Support [Doc. No. 2037]. In fact, they do not discuss her qualifications at all or mention that she is a board-certified urologist with a sub-specialty in Pelvic Floor Medicine and Reconstructive Surgery. Prolapse Report at 7.[1] She has performed "well over 1000" prolapse surgeries and "over 900 sling procedures" to treat SUI. Prolapse Report at 7; TVT Report at 6. She has performed 10 to 20 complete explants and 50-60 revisions or partial removals. Ex. A, Pramudji (4/11/14) Dep. at 54.[2] She has also

[1] Dr. Pramudji submitted two reports in this case, one related to devices to treat pelvic organ prolapse (Gynemesh PS, Prosima and Prolift) (the "Prolapse Report," Exhibit B to Plaintiffs' Motion), and one related to devices to treat stress urinary incontinence (TVT and TVT-O) (the "TVT Report," Exhibit C to Plaintiffs' Motion), (collectively "Reports"). The general opinions set forth in these Reports and challenged here by Plaintiffs related to risks and warnings, design and efficacy and degradation are included in both Reports.

[2] While Plaintiffs relied upon this deposition from the *Huskey* matter, as well as Dr. Pramudji's March 23, 2016 and March 24, 2016 general depositions in this case, they attached cursory

taught surgeons across the country and at national conferences regarding the use of mesh devices and has consulted with medical device companies in the development of slings to treat SUI. Pramudji Prolapse Report at 7; TVT Report at 6. Plaintiffs do not discuss her reliance materials which include a large base of medical literature, including Level 1 evidence such as Cochrane Review meta-analyses assessing thousands of patients, and numerous randomized controlled trials (RCTs), not to mention public statements by medical societies in the fields of urology. Prolapse Report at 20-35; TVT Report at 24-27; 39-41; 44-51; 59-62; Reliance List, attached as Ex. B.[3]

Despite Dr. Pramudji's years of surgical experience and her review of considerable Level 1 peer-reviewed medical literature and RCTs, the Prolapse device IFUs, the TVT device IFUs and professional education materials, *see, e.g.*, Prolapse Report at 8-9; TVT Report at 7-8, Plaintiffs seek to preclude Dr. Pramudji from testifying about the adequacy of the device IFUs, arguing that she is not an expert on regulations governing device manufacturers and is instead relying solely on her experience as a surgeon. Plaintiffs' further seek to preclude her opinions, based upon her years of experience, that the devices are efficacious in design to treat pelvic organ prolapse or stress urinary incontinence and that the product benefits outweigh the product risks. Finally, Plaintiffs attempt again to preclude Dr. Pramudji from offering testimony that the polypropylene mesh products do not degrade in the human body. None of Plaintiffs' arguments has merit, and their Motion should be denied.

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excerpts of her testimony as exhibits to their Motion. Given the nature of this Motion challenging her opinions, Ethicon attaches the full transcripts from each of these depositions in order for the Court to have a full record of Dr. Pramudji's education, training, experience and reliance materials, as well as a full understanding of her testimony in these matters.

[3] While Plaintiffs attached Dr. Pramudji's Reports to their Motion, they did not include her reliance list, Ex. B to those Reports.

- **Product Warnings:** Dr. Pramudji's opinions related to the knowledge of pelvic floor surgeons who use these devices is based on her own education, her experience, her extensive review of the literature summarized in her Reports, and her reading of professional association statements. The legal standard is that Ethicon only has a duty to warn of risks unique to its devices and has no duty to warn of risks commonly known by pelvic floor surgeons. She is qualified to identify those risks.

- **Design.** Dr. Pramudji's design and risk-benefit opinions are based on her extensive experience in the use of these products, her clinical results and her examination of the medical literature, including studies assessing thousands of patients and randomized controlled trials. She is plainly qualified to testify on that subject and on the absence of literature to support Plaintiffs' alternatives.

- **Clinical Experience:** This Court has already previously rejected attempts to exclude practitioners, like Dr. Pramudji, from offering testimony regarding their own experiences with Ethicon's products related to the lack of degradation of the products.

ARGUMENT

I. Standard for admissibility of expert opinion testimony.

Ethicon incorporates by reference the standard of review for Daubert motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 92316, at *3-8 (S.D. W. Va. July 8, 2014).

II. Dr. Pramudji is qualified to address the adequacy of the IFUs and Ethicon's warnings based on her experience and supporting literature and studies.

Dr. Pramudji's opinions related to the IFUs and warning issues are housed not only in her personal education and clinical experience, but also in Level 1 evidence such as Cochrane Review meta-analyses assessing thousands of patients, and numerous randomized controlled trials (RCTs), not to mention public statements by medical societies in the fields of urology. Prolapse Report at 20-35; TVT Report at 24-27; 39-41; 44-51; 59-62; Reliance List, attached as Ex. B.

Plaintiffs' argument on this issue is that Dr. Pramudji did not rely upon FDA regulations or internal protocols at Ethicon concerning her opinion that the devices are not defective in

design. Plaintiffs' Memorandum at 4-5. This argument rests entirely on the supposition that expertise in FDA regulations related to requirements for IFUs is mandatory for these opinions.

Yet, the job of an expert witness is to provide the facts to which the court can apply the law. It is not the expert's job to provide the court with the law. This Court, in fact, has excluded testimony which not only stated facts but also expressed a legal conclusion. *In re Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation (Lewis)*, 2014 WL 186872 (S.D. W. Va. 2014) at *20, *citing United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). The important question here is whether Dr. Pramudji's testimony was consistent with the law to be applied to the case, and not whether she herself could articulate the governing legal standard. If she had attempted to do that, her testimony would have been excluded.

This Court's prior decision with regard to Dr. Pramudji's testimony on product warnings was concerned with testimony from an expert that, because she had not experienced certain risks in her clinical practice, then her opinion that such risks need not be contained in the IFU was improper. *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Memorandum Opinion and Order (*Daubert* Motions), Doc. 265 at 35 (S.D. W. Va. Nov. 20, 2014). That is not what Dr. Pramudji does here. Nor does she testify that, based upon the risks and complications she has seen in her clinical practice, "there are no other possible risks or complications that should have been included." *Mathison v. Boston Scientific Corp.*, 2015 WL 2124991, *27 (S.D. W. Va. May 6, 2015). Instead, her warning opinion and opinion that the IFUs are adequate is tied to the knowledge of pelvic floor surgeons based on their education and experience from performing pelvic surgery. Thus, the circumstances here are different from those in *Bellew*, and her opinions here are proper. *See Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, *4 (S.D. W. Va.

April 28, 2016) (different circumstances may justify a different ruling when *Daubert* challenges are made).

The legal principle that controls here is that a device manufacturer's duty to warn of adverse events is limited to events unique to the device. It does not include a duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 (S.D. W. Va. 2009) (adopting "sophisticated user" defense in §388).

This limitation on the duty to warn is recognized in medical cases as well. There is no duty to warn of risks that implanting surgeons commonly know. *See Brooks v. Medtronic, Inc*., 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community"). In fact, the FDA regulations recognize that information may be omitted from labeling "if, but only if, the article is a device for which directions, hazards, warnings and other information are *commonly known* to practitioners licensed by law to use the device." 21 C.F.R. §801.109(c) (emphasis added).

The device IFUs restrict the class of surgeons who are to use the devices. They contemplate that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence. *See*, *e.g.*, Ex. C, TVT IFU at 28 ("Users should be familiar with surgical techniques for bladder neck suspensions and should be adequately trained in implanting the TVT system before employing the TVT device."); Ex. D, TVT-O IFU at 5 ("Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the

Gynecare TVT Obturator procedure before employing the Gynecare TVT Obturator device."); Ex. E, Prosima IFU at 12 (used only by physicians "familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes"). Pelvic surgeons know that these IFUs are not intended "to be comprehensive" because surgeons have a general base of knowledge about risks of surgery, and thus surgeons would not expect the IFU to be comprehensive. Ex. F, Pramudji (3/23/16) Prolapse Dep. at 110; 112.

So the important question with respect to Plaintiffs' failure to warn claim is what "hazards" are "commonly known" to surgeons familiar with pelvic surgery, including surgery to address pelvic organ prolapse and SUI. Ethicon had no duty to warn of adverse events "commonly known" to those surgeons. Its duty was to warn of adverse events that were unique to the mesh devices. If Plaintiffs intend to argue at trial that Ethicon's IFU failed to disclose certain risks, Ethicon is fully entitled to defend such claims by demonstrating that those risks were obvious to the users of the product (pelvic surgeons), and therefore, did not need to be included.

A. Dr. Pramudji's experience as a urologist and pelvic surgeon renders her qualified to offer her opinions here regarding Ethicon's warnings and IFUs.

Dr. Pramudji is well-qualified to testify to what pelvic surgeons know. She relies on her experience as a urologist with a sub-specialty in pelvic floor medicine and as a pelvic surgeon to discuss what risks of pelvic surgery would be known to such surgeons generally. She has taught other surgeons how to use such devices. She addressed that risks need not be included in the IFU or warnings unless they are clinically significant and that many risks of the use of mesh are also ordinary risks of performing any pelvic floor surgery. Ex. F, Pramudji (3/23/16) Prolapse Dep. at 120-22; Ex. G, Pramudji (3/24/16) Prolapse Dep. at 159-162; Ex. H, Pramudji (3/24/16) TVT Dep. at 38-44. Because of that, telling a surgeon of the risk is not necessary. Ex. F,

Pramudji (3/23/16) Prolapse Dep at 122; Ex. H, Pramudji (3/24/16) TVT Dep. at 47. This relates to adequacy of the IFU because the failure to warn analysis involves a determination of what the user of the product knew. Thus, a surgeon's perspective on what pelvic surgeons know directly correlates with risks that do not need to be in the IFU. *See In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings . . . ." (internal quotations and brackets omitted)).

This Court has permitted experts to opine about risks they perceive from surgery using mesh and whether those risks are covered by the applicable IFU. *See Huskey*, 29 F. Supp. 3d 691, 703, 719 (S.D. W. Va. 2014) (Drs. Rosenzweig and Blaivas adequately experienced physicians to testify to risks of surgery and whether the risks were addressed in the IFU despite lack of expertise in FDA regulations or standards governing device warnings); *Trevino v. Boston Scientific Corp.*, 2:13-cv-01617, 2016 WL 1718836, at *13-14 (S.D. W. Va. April 28, 2016) (Dr. Shull permitted to testify on adequacy of DFUs "from a clinician's perspective"). Here, Dr. Pramudji relies on her experience as a pelvic surgeon to state that pelvic surgeons know certain risks are associated with pelvic surgery, with or without mesh augmentation, and thus their inclusion in the IFU would not be informing the user of the product.

Plaintiffs specifically asked Dr. Pramudji about lists of risks, including erosion, chronic pain syndrome, dyspareunia, the need for additional surgical intervention to address complications, the potential for life-changing complications, pelvic pain (Ex. F, Pramudji (3/23/16) Prolapse Dep. at 120-22); bleeding, hematoma, incontinence, urinary frequency, retention or obstruction, acute/chronic pain, wound dehiscence, nerve damage, recurrent

prolapse, foreign body response, pelvic pain, dyspareunia, contraction of tissue, damage to nearby organs, neuromuscular problems (Ex. G, Pramudji (3/24/16) Prolapse Dep. at 160); dyspareunia that may not resolve, difficulty in removing mesh if required, seroma, urge incontinence, adhesion formation, atypical vaginal discharge and death (Ex. H Pramudji (3/24/16) TVT Dep. at 38-43). As to each of these risks (except for erosion), Dr. Pramudji noted it was also a risk of any pelvic floor surgery, with mesh augmentation or without. *Id*. Dr. Pramudji testified that exposure or integration into tissues making removal difficult are also risks that can occur in surgeries without mesh because sutures can cause the same complications. Ex. H, Pramudji (3/24/16) TVT Dep. at 40-43.

Because of this, Dr. Pramudji could state objectively that any failure to include these particular risks in the IFU did not make the IFU inadequate since pelvic floor surgeons know these risks. *See* Ex. H, Pramudji (3/24/16) TVT Dep. at 47 ("pelvic surgeons are already familiar with all of these adverse reactions."); Ex. G, Pramudji (3/24/16) Prolapse Dep. at 162 ("they are part of the body of knowledge of pelvic surgeons"); Ex. F, Pramudji (3/23/16) Prolapse Dep. at 122 ("I think those are risks that pelvic surgeons would anticipate, because as I stated, most of those risks, with the exception of the erosion, are risks of pelvic surgery."). She further can testify that the lack of inclusion of such risks as adverse events would not "deprive a reader [surgeon] or mislead a reader [surgeon] of what the risks and benefits" of the devices were when the IFUs were published. *See, e.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 2d 691, 719 (S.D. W. Va. 2014) (addressing permissible scope of testimony from plaintiff's expert urologist) (quoting *In re Diet Drugs Prods. Liab. Litig.*, 2000 WL 876900, at *11 (E.D. Pa. June 20, 2000)).

Plaintiffs' assert that expert opinion based on experience without an explanation of how that experience leads to the conclusion reached is improper. Plaintiffs' Response at 7. That did

not happen here. Dr. Pramudji was clear that literature and studies support her opinion, including Level 1 literature analyzing thousands of patients and RCTs, along with years of education and medical school training and her years of practice. Prolapse Report at 5, 19, 38, 47; TVT Report at 4-5, 15, 68-69. She therefore establishes a reliable basis for her opinions. This Court has recognized that experience in clinical practice is a proper basis for expert opinion. *Trevino*, at *14.

Contrary to Plaintiffs' assertion, Dr. Pramudji's opinions are not "based solely on her subjective belief and her status as an 'expert'." Plaintiffs' Memorandum at 4. It is instead based on years of education, training, and clinical experience as well as a thorough review of medical studies and literature. She asserts that certain information is not necessary in the IFU because trained surgeons know the risk. And given that Ethicon's IFUs direct that only pelvic floor surgeons trained in implantable materials should use the mesh products, the general knowledge of pelvic floor surgeons is wholly relevant to the inquiry of what should be in the IFU.

B. Dr. Pramudji's opinions were never intended to rely on FDA regulations; nor do they need to in order to be admissible.

Dr. Pramudji is not offered to testify concerning the regulations applicable to product warnings or whether Ethicon complied with those regulations. Nor will she address internal Ethicon protocols related to product warnings or what risks Ethicon knew when the IFUs were drafted. Rather, Dr. Pramudji's testimony is based on her perceptions as a pelvic surgeon, her knowledge of what risks a pelvic surgeon would know and medical literature and studies concerning risks.

Plaintiffs attempt to make much of the fact that Dr. Pramudji does not know if Ethicon warned of "all known risks," yet this is not the standard under a failure to warn analysis. Plaintiffs' Memorandum at 5. Nor is it the standard under the governing regulations related to

prescription medical devices. *See* 21 CFR § 801.109(c) (applicable to "Prescription devices") (warning need not include "directions, hazards, warnings, and other information [ ] commonly known to practitioners licensed by law to use the device."). This comports with the learned intermediary doctrine as well. Given that a manufacturer has no duty to warn of risks known or obvious to those using its product, the general knowledge of pelvic floor surgeons is the pinnacle inquiry. *See, e.g.,* Restatement (Third) of Tors: Product Liability §2 cmt. j (1998); Restatement (Second) of the Law of Torts §402A cmt. j; American Law of Product Liability 3d §32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4th Cir. 1990).

Plaintiffs selectively cite testimony out of context in support of the false notion that Ethicon's employees supposedly admitted that all risks (regardless of whether obvious) must be disclosed in the IFU. Plaintiffs' Memorandum at 6. Yet Dr. David Robinson testified that "that's not true" and that physicians "shouldn't depend on [the IFU] as the sole source of their information" regarding product risks. David Robinson, M.D., Dep. at 488:7- 9, 489:12-17 (Ex. G to Plaintiffs' Motion [Doc. 2035]). As further noted by Dr. Charlotte Owens: "I would say that we listed the adverse reactions that we knew were adequate and sufficient for this document [the IFU]. . . . Physicians will not rely solely on the IFU for making their decisions . . . and ultimately will use their training, education, and experience, plus this document, to decide if they want to use it. . . . I don't think you're giving surgeons enough credit. Surgeons don't have to figure out the complications of an area that they operate. Surgeons are trained to know the complications of the area in which they operate." Charlotte Owens, M.D. Dep. at 310:10-13, 261:12-14, 262:2-5, 262:20-25 (Ex. F to Plaintiffs' Motion [Doc. 2035]).

This supports Dr. Pramudji's testimony that, while she did not review every email discussion or document ever created by Ethicon's medical/regulatory affairs department, the

purpose of those departments is to consider everything that could possibly happen. Ex. F, Pramudji (3/23/16) Prolapse Dep. at 115 (Medical affairs is "going to have multiple discussions and opinions and bouncing things back and forth."). Yet adequate warnings need not cover every potential or remote risk, particularly when the surgeon knows that such risks exist.

Nor does the fact that Dr. Pramudji does not know every step of the protocol within Ethicon to determine substantial risks defeat her testimony here. Dr. Pramudji is not offering the opinion that because she has not seen a risk, then it need not be in the warning. Rather, she is testifying that the litany of risks raised by Plaintiffs includes risks that are known to surgeons who perform pelvic surgeries. And most are the same risks whether mesh augmentation is used or not (except for erosion, which is listed in the IFUs).

Plaintiffs argue that Dr. Pramudji should be precluded from testifying about product warnings because she "has no knowledge of FDA requirements and no knowledge of industry standards." Plaintiffs' Memorandum at 4. As indicated above, while it is true that Dr. Pramudji does not have specialized knowledge about FDA regulations, Dr. Pramudji is competent to testify about how Ethicon's IFUs would be perceived by pelvic surgeons. This Court has recognized that where an expert is not relying on the regulatory standards for warning opinions, addressing risks perceived in clinical practice and whether the warning conveys such risks are within an expert's realm to make the comparison. *Trevino*, at *30. That is what Dr. Pramudji does here as it relates to the knowledge that pelvic surgeons have. She evaluated a host of risks that Plaintiffs urge should have been contained in the IFUs and, applying her clinical experience and education, determined whether those risks are ones that pelvic floor surgeons would have known, thus dispensing with the need for a specific warning in the IFU.

Since Dr. Pramudji is not offering testimony that the IFU was adequate for regulatory or FDA purposes, but instead opines that pelvic surgeons would have known that these risks exist just in performing pelvic surgery, then her opinion that the IFU was adequate when evaluating it from a surgeons' point of view is relevant and reliable.

III. Dr. Pramudji is Qualified to Opine on the Safety and Efficacy of the Devices and their Design as it Relates to Such.

Plaintiffs recognize early in their Memorandum that Dr. Pramudji's design opinions are related to safety and efficacy, i.e., the products as designed "have a positive benefit to risk profile." Plaintiffs' Memorandum at 3. For a surgeon using a medical device, the propriety of a product design is assessed in terms of the risks and benefits of the device, including the utility and the usefulness of the device as employed in the field. Her determination of lack of product defect is tied to the product's usefulness and safety not only in her hands, but as set forth in Level 1 evidence, randomized controlled trials and her review of systematic reviews and meta-analysis as well as Cochrane reviews. Pramudji Prolapse Report at 20-35; Pramudji TVT Report at 24-27; 39-41; 44-51; 59-62.

Nowhere does Dr. Pramudji suggest that she will discuss the design of the product in terms of Ethicon's protocols, FDA requirements or regulations, chemical content or polymer structures. Nor does her Report or testimony indicate that she intends to opine on failure modes effects analyses as related to product design. Plaintiffs' Memorandum at 9. And there is no requirement under *Daubert* that Dr. Pramudji review internal company design documents for her methodology to be reliable, as Plaintiffs argue, and this Court has never required as much. Although Plaintiffs rely on *Winebarger* to support their argument, that reliance is misplaced. Plaintiffs' Memorandum at 10. In that case, Dr. Shull sought to opine that the company had failed to follow its own internal protocols and that those protocols were lacking, even though he

had never seen any standard operating procedures for the company's medical device development or any of the internal design protocols. *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015). Dr. Shull's methodology was thus lacking "a necessary piece of data" and unreliable "regardless of the literature he has reviewed or the experience he has gained" because his methodology failed to include a review of the documents that would support his internal-protocols opinion. *Id.* By contrast, Dr. Pramudji here is not attempting to testify that Ethicon followed its own internal design protocols or that they were otherwise adequate. Accordingly, her opinion does not require a review of internal design protocols.

Nor does a defective design claim necessarily flow from such documents. Instead, whether a device is defective is assessed upon it safety, efficacy, usefulness, function, utility and desirability in the field in the hands of intended users, like Dr. Pramudji. Thus, Dr. Pramudji's opinions rely on her years of education and experience related to the pelvic floor anatomy and the use of mesh devices to treat prolapse and SUI, as well as on her clinical observations in performing hundreds of surgeries with such implantable devices, both implanting them and explanting them. Prolapse Report at 7; TVT Report at 6. In addition, Dr. Pramudji's opinions regarding the safety, efficacy, function, utility and desirability of the device in the field are based on her extensive review of the medical literature as set forth throughout her Reports. For example, in her TVT Report, she discusses the design of the TVT which is catalogued in the peer reviewed medical literature available to pelvic floor surgeons like herself. *See generally*, TVT Report at 22-27, citing Petros PE, Ulmsten UI., *An integral theory and its method for the diagnosis and management of female urinary incontinence*, Scand J Urol Nephrol Suppl. 1993; 153:1-93; Ulmsten U, et al., *An ambulatory surgical procedure under local anesthesia for*

treatment of female urinary incontinence, Int Urogynecol J Pelvic Floor Dysfunct. 1996; 7:81-5; Falconer C, et al., *Influence of different sling materials on connective tissue metabolism in stress urinary incontinent women*, Int Urogynecol J Pelvic Floor Dysfunct. 2001; 12 Suppl 2:S19-23. Similarly, in her Prolapse Report, she discusses the design of the Prolift device and in particular the medical literature supporting her opinions regarding design defect. *See generally*, Pramudji Prolapse Report at 17-21, citing Berrocal 2004.

Plaintiffs create a straw man regarding Dr. Pramudji's intended testimony on this topic by discussing certain Ethicon documents like design failure modes analysis, process failure modes analysis, and failure modes effects analysis. Plaintiffs' Memorandum at 9-12. Dr. Pramudji is not offering opinions on Ethicon's risk assessments or Ethicon's design protocols. Her design opinion is tied to her considerable clinical experience with the products and the risks and benefits of those products in that vast experience and as set forth in the extensive medical literature that she has reviewed as part of her assessment of the devices. She testified to such: "My opinions would go to how I feel the design is based on use in my hands and based on patient results. So I feel very confident and familiar with evaluating the design based on those parameters." Ex. G, Pramudji (3/24/16) Prolapse Dep at 186.

Dr. Pramudji has demonstrated that, as an experienced pelvic surgeon, she has expertise to testify as to whether the design of the devices was adequate to address the conditions for which they were being used, i.e., she can address the design in terms of the safety and efficacy of these devices. Ex. F, Pramudji (3/23/16) Prolapse Dep. at 63; Ex. G, Pramudji (3/24/16) Prolapse Dep. at 257-58; Ex. H, Pramudji (3/24/16) TVT Dep. at 67; Prolapse Report at 4-5; 34; 43; TVT Report at 7-8;15; 33. She is able to identify and explain that the design of products was effective in meeting the needs of her patients. Her opinions relate to the design *issue* as part of a

risk-utility analysis, but are not design opinions in the artificial sense set forth by Plaintiffs of a product design under certain Ethicon protocols or FDA requirements or regulations. Instead, she draws from her clinical experience and the relevant medical literature to determine that the product benefits outweigh the product risks and that it has utility and usefulness among other features. This Court has determined that such experience is sufficient for opinions of this nature. *See Trevino*, at *6.

Given her experience, and the opposing opinions of Plaintiffs' experts that are also based on their experience, it is reliable and relevant for her to testify that in her hundreds of uses of these products, the design was efficacious in treating difficult pelvic floor disorders. Pramudji TVT Report at 69; Pramudji Prolapse Report at 6.

Plaintiffs argue that Dr. Pramudji's opinions on risks and benefits should be excluded because she cannot cite to specific complication rates. Plaintiffs' Memorandum at 13-14. However, any claimed lack of support (which Ethicon disputes), is not required. *Winebarger*, 2015 WL 1887222, at *34 (expert's inability to provide "exact statistics" about the outcome of his patients did not render his personal experience opinions unreliable as "such detail is not required under *Daubert* to opine as to '*large-scale* safety and efficacy of the [ ] device.'"). Any asserted failure in her analysis is better addressed on cross examination than by excluding the testimony. *Trevino*, at *23. This is especially true where Dr. Pramudji relies extensively on high level and scientifically reliable medical studies and literature to support her conclusions as set forth in her Reports, and not simply on rough calculations discussed during her deposition. *See* Ex. G, Pramudji (3/24/16) Dep. at 239.

IV. Dr. Pramudji's Degradation Opinions are Well-Supported and Proper.

Dr. Pramudji has performed 10 to 20 complete explants and 50-60 revisions or partial removals. Ex. A, Pramudji (4/11/14) Dep. at 54. She looked at the material she explanted and found no degradation. Ex. A, Pramudji (4/11/14) Dep. at 140. She has looked at pictures of polypropylene under a microscope and has reviewed images of explanted material provided to her by pathologists. Ex. A, Pramudji (4/11/14) Dep. at 139-140. In her review of 10-20 slides of explanted mesh, she found no evidence of degradation. Ex. A, Pramudji (4/11/14) Dep. at 140.

This Court has previously permitted Dr. Pramudji to testify regarding her personal clinical experience related to the lack of degradation of pelvic mesh products. *Huskey*, 29 F. Supp. 3d 691, 727 (S.D. W. Va. 2014); *Bellew*, Memorandum Opinion and Order (*Daubert* Motions), at 33. This Court recently reiterated its conclusion that an expert's reliance on scientific articles combined with clinical experience constitutes reliable, scientific methodology to offer an opinion concerning degradation of polypropylene mesh. *Trevino*, at *14-15; *106. Dr. Pramudji seeks to do the same here.

Recognizing that this Court has permitted such opinions in *Huskey*, Plaintiffs claim that Dr. Pramudji's opinions here go beyond what this Court allowed there. Plaintiffs' Memorandum at 15. Yet, Plaintiffs rely solely on Dr. Pramudji's testimony from the *Huskey* case in support of their motion to exclude her allegedly broader-than-*Huskey* degradation opinions. Plaintiffs' Memorandum at 15-17. The opinions on degradation that they attack here are the *very same ones* challenged in *Huskey* that this Court allowed.

Dr. Pramudji is qualified by education, training and experience to offer the opinion that polypropylene mesh does not degrade. Plaintiffs again build a straw man to try to preclude this testimony by arguing that Dr. Pramudji does not know the "scientific, chemical or structural make-up" of polypropylene. Plaintiffs' Memorandum at 15-16. Such specific information is not

needed in order to discuss the fact that she has seen no degradation in her clinical practice and that the literature and studies do not support Plaintiffs' theory.

Dr. Pramudji's opinion is further supported by the literature and studies she cited that support her position. Pramudji Prolapse Report at 35-36; Pramudji TVT Report at 62-65. She testified that she relied upon dozens of articles and studies in formulating this opinion, along with her personal experience as a urologist and surgeon. Ex. A, Pramudji (4/11/14) Dep. at 39-40. She is "always reviewing the literature, looking for all the information that I can regarding the sling and mesh cases." Ex. A, Pramudji (4/11/14) Dep. at 39. She testified that the literature does not support degradation and that studies show that in millions of women, polypropylene mesh has not been shown to degrade. Ex. A, Pramudji (4/11/14) Dep. at 146, 148.

According to Dr. Pramudji, the "literature definitely supports it [no degradation] when we don't see problems that can be related back to degradation in the literature." Ex. F, Pramudji (3/23/16) Prolapse Dep. at 71. In the studies she cites, "where they remove the mesh, the mesh is there. You know, it's not -- it doesn't disappear. It doesn't degrade over time. I mean, if Prolene degraded, they would not use it in cardiac surgery to rely on sewing together arteries." *Id*. at 76. And this is supported in her personal experience removing mesh, "it's not like you see it disintegrating. It's not falling apart in front of your eyes." *Id*.

Plaintiffs challenge Dr. Pramudji's literature and studies, arguing that because remote studies exist that are purportedly contrary to her opinions, then her opinions must be excluded. Plaintiffs' Motion at 16-17. Dr. Pramudji admits such remote studies exist. She just finds them unpersuasive in light of the vast high-level information and literature to the contrary. Ex. F, Pramudji (3/23/16) Prolapse Dep. at 76-77. Further, the existence of claimed contrary studies is fodder for cross examination, not a basis to exclude Dr. Pramudji's opinions as unreliable when

they are based both on her considerable personal experience as well as medical literature and studies. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("the court need not determine that the expert testimony a litigant seeks to offer into evidence is irrefutable or certainly correct.").

As to Plaintiffs' argument that Dr. Pramudji did not personally conduct tests or look at polypropylene under a microscope, such personal testing is not a prerequisite to admissibility, as this Court found in *Huskey*. *See* Plaintiffs' Memorandum at 16. Here, Dr. Pramudji's opinions are the result of her extensive education, training, experience and appropriate reliance upon applicable medical literature. These opinions need not be accompanied by her personal testing.

Plaintiffs' argument for exclusion also relies upon Dr. Pramudji's alleged lack of practical experience applying her chemical engineering degree; lack of work in the general field of chemical engineering; lack of specialized education or training related to polypropylene; and lack of education or training on the structural make-up of Ethicon medical devices or components. Plaintiffs' Memorandum at 15-16. All of this overlooks the fact that Dr. Pramudji is a board-certified urologist who specializes in pelvic floor disorders and who has performed hundreds of surgeries utilizing these mesh devices and has reviewed the medical literature, including the unreliable literature that Plaintiffs' experts rely upon. She has been permitted in the past to testify to the lack of evidence of degradation in her clinical practice. She testifies to the vast body of medical literature that supports her. To the extent that Plaintiffs disagree with her conclusion, then cross examination, and not exclusion, is the appropriate vehicle to address that.

CONCLUSION

For the reasons set forth above, the Court should deny Plaintiffs' Motion to Exclude Certain Opinions of Christina Pramudji, M.D.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 9, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
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